

County of San Diego
Health and Human Services Agency (HHS)

Chapter: Policy Guidelines, and Program Development
Key Words: Evaluation, Research, Data, Grant, Request

SUBJECT: Guidelines for Authorizing Research	ITEM NUMBER	HHSA-H-4
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REFERENCE:

Title 45 CFR, Parts 46; 160 and 164; HHSA-G-1.9 HHSA Agreements

PURPOSE:

To establish a process for authorization of requests to conduct research involving employees, clients or patients, contractors, records, or locations of the County of San Diego Health and Human Services Agency (HHS); and to monitor ongoing research activities.

BACKGROUND:

Research of government programs and operations has led to a wide range of improvements in the health and well-being of San Diego County residents. Research is systematic investigation, including research development, testing and evaluation, designed to develop or contribute to general knowledge (45 CFR, Part 46, §46.102).

Professional research standards guide the design and conduct of research, setting standards for how researchers gather and analyze information. Research on government operations and programs often involves the analysis of information about the individuals who receive County services. HHS is responsible for managing, protecting, and providing appropriate access to the information it collects, including identification of sensitive and/or confidential information and protection of this information from open exchange. Research that results in the expenditure or use of HHS resources must add value to the organization or to the programs and services it administers. This research should be selected based on existing County priorities, the need to test innovative new pilot programs and models, and the potential for program evaluation to influence major policy and budgetary decisions. The research should cause no foreseeable financial, reputational, or other risk, to the County or the people it serves.

Evidence-based policymaking is a potent tool, putting test solutions on the table and bridging divides using sound analysis and data. This introduces the following benefits:

- Focusing on proven programs that deliver better outcomes for residents
- Strengthening accountability and transparency
- Encouraging sound stewardship of public resources
- Promoting a culture of learning and innovation, continuously testing new approaches, and adapting to new situations.

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POLICY:

All persons, organizations, and institutions planning to conduct research involving County of San Diego HHSa resources shall obtain written authorization from the Director of the associated HHSa Department/Office, HHSa Compliance representative, and the Director of the Office of Strategy and Innovation (OSI) prior to the start of the research and when there are amendments to research practices, policy, data, or timelines. Each respective Department or Office may develop additional internal policies and/or procedures that are more specific as necessary to guide the research review and oversight in their organizations.

Researchers must:

1. Complete HHSa's application process and secure HHSa approval prior to conducting research involving HHSa staff or clients, including staff and clients at County-funded sites run by County contractors and prior to conducting research when there are amendments to the research application.
2. Comply with ongoing communication guidelines during the implementation of the research study.
3. Comply with the terms of agreements specified in the signed research application and any additional HHSa Agreements associated with this research.
4. Comply with all requirements following applicable federal, State, and local laws and regulations.
5. Submit draft and final reports, articles, and other documents for review prior to publication.

PROCEDURES:

See (APPENDIX A) INSTRUCTIONS FOR RESEARCHER: PROCEDURES FOR AUTHORIZING RESEARCH USING HHSa RESOURCES.

See (APPENDIX B) INSTRUCTIONS FOR HHSa DEPARTMENT/OFFICE(S).

See (APPENDIX C) AMENDMENT FORM FOR RESEARCH.

QUESTIONS/INFORMATION:

Contact Office of Strategy and Innovation, OSI.Research.HHSa@sdcounty.ca.gov.

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CROSS-REFERENCES:

[Accounting of Disclosures of Protected Health Information \(HHS L-03\)](#)
Policy [HHSA-G-1.9 HHS Agreements \(Source: Agency Contract Support\)](#)
[Communication Guidelines \(HHS-E-4\)](#)

APPENDIX

[APPENDIX A – INSTRUCTIONS FOR RESEARCHER: PROCEDURES FOR AUTHORIZING RESEARCH USING HHS RESOURCES](#)

[APPENDIX B – INSTRUCTIONS FOR HHS DEPARTMENT/OFFICE\(S\)](#)

[APPENDIX C – AMENDMENT FORM FOR RESEARCH](#)

Approved:

3/23/22
Date



Nick Macchione, FACHE
Agency Director
Health & Human Services Agency